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UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

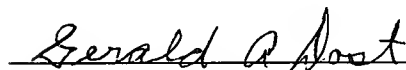
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Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,983,395, which issued January 8, 1991, was filed on November 24, 1995, under 35 U.S.C. § 156. The term subsequent to July 18, 2006, the expiration date of U.S. Patent No. 4,849,224, filed November 12, 1987, has been disclaimed.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.


Gerald A. Dost
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